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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,960	01/30/2004	Evan Gustow	029318-0999	2511
31049 7590 08/07/2007 ELAN DRUG DELIVERY, INC. C/O FOLEY & LARDNER LLP 3000 K STREET, N.W. SUITE 500 WASHINGTON, DC 20007-5109			EXAMINER GEORGE, KONATA M	
			ART UNIT 1616	PAPER NUMBER
			MAIL DATE 08/07/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/766,960

Applicant(s)

GUSTOW ET AL.

Examiner

Konata M. George

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-107 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-107 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

Claims 1-107 are pending in this application.

### ***Action Summary***

1. The finality of the office action dated February 6, 2007 is being vacated in lieu of the rejection below.
2. The rejection of claims 1, 2, 4, 6-8, 10 and 11 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 5-7, 9-14 and 18-20 of U.S. Patent No. 6,592,903 in view of U.S. Patent No. 6,696,091 is hereby withdrawn as applicant has filed a terminal disclaimer.
3. The provisional rejection of claims 1-17, 24-27, 29-33, 35, 36, 39-56, 58, 65, 77-90 and 92 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 10, 11, 14, 16, 17, 19, 21-26, 28, 29, 32-38, 41, 46-50, 59, 60, 62, 63, 65, 67-70, 76, 77, 89, 90, 93, 95, 96, 96, 100-104 and 107 of copending application 10/619, 539 in view of U.S. Patent No. 6,696,091 is being maintained for the reasons stated in the office action dated February 6, 2007.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where

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the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-17, 24-27, 29-33, 35, 36, 39-56, 58, 65, 77-90 and 92 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 10, 11, 14, 16, 17, 19, 21-26, 28, 29, 32-38, 41, 46-50, 59, 60, 62, 63, 65, 67-70, 76, 77, 89, 90, 93, 95, 96, 98, 100-104 and 107 of copending Application No. 10/619,539 in view of US Patent No. 6,696,091. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are directed towards a composition comprising an active agent having a particles size of less than 2000 nm and at least one surface stabilizer. The difference between the two is the selection of the active agent and the addition of an osmotically active crystal growth inhibitor in '539. Claim 29 teaches that anti-epileptics can be used as an active agent. US Patent 6,696,091 is be relied upon to teach that topiramate can be used to treat epilepsy (col. 2, lines 17-20). Therefore, it would

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have been obvious to one of ordinary skill in the art to use the teachings of '091, that topiramate can be used treat epilepsy in the invention of '539, which teaches the use of anti-epileptics drugs in nanoparticle compositions. With respect to the addition of an osmotically active crystal growth inhibitor, the composition of the instant application is not limited to what is being claimed. The open language of comprising allows additional ingredients to be present. Furthermore, the osmotically active crystal growth inhibitors as claimed such as glycerol, can be used as a surface-active agent (see claim 17 of '405).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Applicant's arguments filed May 4, 2007 have been fully considered but they are not persuasive.

Applicants supplied a terminal disclaimer over US Patent No. 6,696,091 in an attempt to overcome the rejection. A terminal disclaimer over copending Application No. 10/619,539 will overcome the rejection not over the US patent cited.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-107 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

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matter which applicant regards as the invention. Applicants use the phrase "less than about" or "greater than about" in the claims when describing particle size, viscosity, relative bioavailability, etc. It is unclear to the examiner if it is "less than", "greater than" or "about" the values that are being claimed.

7. Claims 11, 20, 53, 61 and 87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants in the claims recite the phrase "derivatives". Webster's Dictionary defines a derivative as "a substance derived from, or of such composition and properties, that it may be considered as derived from, another substance by chemical change, esp. by the substitution of one or more elements or radicals". Based on this definition it is unclear what the derivative is.

### ***Conclusion***

8. Claims 1-107 are rejected.

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***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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